SEP 5 2002 K022766

Special 510(k): Device Modification
SIEMENS Medical Information Bus (MIB/MIBII) Protocol Converters

---

510(k) SUMMARY
as required per 807.92(c)

Submitters Name, Address:

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: Connie Hertel, Director, QA/RA
Contact person for this submission: Penelope H. Greco
Date submission was prepared: August 19, 2002

Trade Name, Common Name and Classification Name:

A. Trade Name:

Siemens Medical Information Bus (MIB, MIB II, MIB Duo) Protocol Converters

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Transducer Signal amplifier and conditioner	73 DRQ	II	21 CFR 870.2060

Legally Marketed Device Identification:

Siemens INFINITY MIB II Duo: 510(k) K012461
Siemens INFINITY MIB II Protocol Converter: 510(k) K010640
Siemens Medical Information Bus (MIB) Protocol Converter:
510(k) K970368, K973222, K991661, K003248, K020277
Siemens MVWS and INFINITY Network with INFINITY VentViewer (K003246)

Description of Modification:

Siemens Medical Information Bus (MIB) Protocol Converters have received numerous 510(k) clearances for connectivity to third party devices. The release of MIB VF2 software and MIB II VA2 software, along with device specific accessory cables enables MIB connectivity of the following devices to the INFINITY modular monitors (SC 9000/SC7000/SC9000XL/SC8000):

Puritan Bennett 840 ventilator
Hamilton Galileo ventilator
Abbott Q2
Sensormedics Micro Gas 7650

These connections enable the display of device specific data on an INFINITY modular monitor. Data from the Puritan Bennett 840 and Hamilton Galileo ventilators can also be displayed on the VentCentral application (K003246) of the MultiView WorkStation.

The modifications described have not altered the fundamental technology of the MIB/MIBII Protocol Converters.

The intended use and indications of the MIB with VF2 software and the MIBII with VA2 software, as described in its labeling, are the same as the intended uses and indications for the MIB/MIBII unmodified predicate devices.

Intended Use:
The Siemens Medical Information Bus (MIB / MIB II / MIB Duo) Protocol Converters are intended for use in an environment where patient care is provided by healthcare professionals (Physician, Nurse, Technician) when the professional determines that a third party medical device should be connected to a Siemens Modular Monitor for display of data.

Connectable devices include: Siemens SV 300 ventilator, Siemens Servo*i* Ventilator, Baxter Vigilance blood gas/continuous cardiac output monitor, Siemens SV900 ventilator, Draeger Evita II ventilator, Draeger Evita IV ventilator, Draeger Babylog ventilator, Puritan Bennett 7200 ventilator, Puritan Bennett 840 ventilator, Hamilton Galileo ventilator, Draeger Narkomed II Anesthesia System, Draeger Narkomed IV Anesthesia System, Draeger Julian Anesthesia Machine, Ohmeda 7900 Anesthesia Machine, Abbott Oximetrix 3 Blood Gas Analyzer, AVL Medical Instruments: Opti Critical Care Analyzer Portable Blood Gas Analyzer, Optical Sensors Inc.: OSI – Optical CAM, VIA Medical: VIA V-ABG1 Blood Gas Chemistry Monitor; and Aspect A-2000 BIS, Abbott Q2, and Sensormedics Micro Gas 7650.

Assessment of non-clinical performance data for equivalence: Section J

Assessment of clinical performance data for equivalence: Not applicable

Biocompatability: Not applicable

Sterilization: Not applicable

Standards and Guidances: 1073.3.1 Medical Device Communications-
Transport Profile-Connection Mode
1073.3.2 – 2000 IEEE Standard for Medical Communications
Transport Profile – IrDA Based – Cable Connected

Siemens Medical Solutions USA, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 5 2002

Siemens Medical Solutions USA, Inc.
c/o Ms. Penelope H. Greco
Regulatory Submissions Manager
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923

Re: K022766
Trade Name: Siemens Medical Information Bus (MIB) Protocol Converters
Regulation Name: Arrhythmia Detector and Alarm; Oximeter
Regulation Number: 21 CFR 870.1025 and 870.2700
Regulatory Class: Class III (three)
Product Code: DSI and DQA
Dated: August 19, 2002
Received: August 21, 2002

Dear Ms. Greco:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

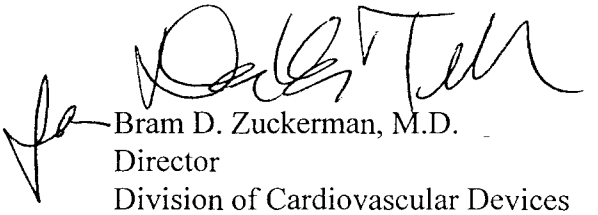
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: Siemens Medical Information Bus (MIB) Protocol Converters

Indications for Use:

The Medical Information Bus (MIB) Protocol Converters (MIB, II & MIB Duo) are indicated for use in an environment where patient care is provided by healthcare professionals (Physician, Nurse, Technician) when the professional determines that third party medical devices that provide data should be connected to a Siemens INFINITY Modular Bedside Monitor (SC 9000 / SC 7000 / SC 8000 / SC 9000XL) for display. Such devices include:

Siemens SV 300 ventilator
Siemens Servo*i* ventilator
Baxter Vigilance blood gas/CCO monitor
Siemens SV900 ventilator
Draeger Evita II ventilator
Draeger Evita IV ventilator
Draeger Babylog ventilator
Puritan Bennett 7200 ventilator
Puritan Bennett 840 ventilator
Hamilton Galileo ventilator
Draeger Narkomed II Anesthesia System
Draeger Narkomed IV Anesthesia System
Draeger Julian Anesthesia Machine
Ohmeda 7900 Anesthesia Machine
Abbott Oximetrix 3 Blood Gas Analyzer
Abbott Q2 CCO monitor
AVL Medical Instruments: Opti Critical Care Analyzer, Portable Blood Gas Analyzer
Optical Sensors Inc.: OSI – Optical CAM
VIA Medical: VIA V-ABG1 Blood Gas Chemistry Monitor
Aspect A-2000 BIS Monitor*
Sensormedics Micro Gas 7650

Note: *The SC 9000 does not support communication with the Aspect BIS Monitor

MRI Compatibility Statement:
The MIB, MIB II and MIB DUO Protocol Converters are not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022464